

REMARKS

This Amendment is submitted in reply to the Non-Final Office Action mailed on August 5, 2009. No fees are due herewith this Amendment. The Director is authorized to charge any fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712038-00306 on the account statement.

Claims 1, 4, 7-11, 14, 18-21 and 24-33 are pending in this application. Claims 2-3, 5-6, 12-13, 16-17 and 21-26 were previously canceled or withdrawn. In the Office Action, Claims 1, 4, 7-11, 14, 18-20 and 27-33 are rejected under 35 U.S.C. §§112 and 103. In response, Claims 11, 27 and 32-33 have been amended. The amendments do not add new matter. In view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be reconsidered and withdrawn.

In the Office Action, Claims 1, 4, 7-11, 14, 18-20 and 27-33 are rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. Specifically, the Patent Office alleges that the claims recite a “cooling agent” and the instant specification defines “cooling agent” as a “non-menthol cooling agent.” However, the Patent Office also alleges that the specification also provides that the cooling agent may be selected from “menthol, methol glyceryl ether, N,2,3-trimethyl-2-isopropyl-butanamide and menthyl glutarate or combination[s] thereof.” See, Office Action, page 2, line 20-page 3, line 5. In response, Applicants have amended the specification to delete the paragraph at page 4, lines 3-5. The deletion of the paragraph does not add new matter. Indeed, Applicants respectfully submit that the skilled artisan would understand that the deleted paragraph was included in the application by mistake and without any deceptive intent.

For example, the Manual of Patent Examining Procedure (“MPEP”) states that “[a]n amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of error in the specification, but also the appropriate correction.” See, MPEP, §2163.07 (citing *In re Oda*, 443 F.2d 1200 (CCPA 1971)). In the case of *In re Oda*, the Court found that Applicants had sufficiently demonstrated that the foreign language translation from “nitric acid” to “nitrous acid” was in error. Applicants demonstrated such error via the submission of arguments and an affidavit from a skilled artisan. 443 F.2d at 1205-1207.

Similarly, one of ordinary skill in the art would immediately appreciate that that the paragraph at page 4, lines 3-5 in the specification was included erroneously by Applicants. For example, Applicants explicitly defined “cooling agents” in the specification as “non-menthol cooling agents.” See, specification, page 1, lines 20-21. Applicants specifically defined this phrase in accordance with Applicants right to be her own lexicographer. Specifically, where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301 (Fed. Cir. 1999). Accordingly, Applicants intention was clearly to define “cooling agents” as “non-menthol cooling agents.”

Further, there are several locations in the specification where Applicants provide examples of what may be used as a “cooling agent.” For example, in the specification at least page 2, line 26-page 3, line 2 and page 3, lines 20-25, Applicants state that “cooling agents” may include N-ethyl-p-menthane-3-carboxamide, N,2,3-trimethyl-2-isopropyl-butanamide, menthyl glutarate, menthyl succinate, menthol PG carbonate, menthol EG carbonate, menthyl lactate, menthone glyceryl ketal, menthol glyceryl ether, 3,3,5-trimethylcyclohexanol, isopulegol, and combinations thereof. Applicants note that menthol is not included in the listing of possible “cooling agents.” In addition, the specification also clearly requires, in an embodiment, Erospicata oil, a cooling agent and menthol. See, page 1, lines 14-21; page 4, lines 1-2; Table 6. Applicants submit that it would not make sense to require these three ingredients if menthol were intended to be included as a cooling agent.

For at least the above-mentioned reasons, Applicants respectfully submit that the deletion of the above-mentioned paragraph does not constitute new matter and that Claims 1, 4, 7-11, 14, 18-20 and 27-33 fully comply with the requirements of 35 U.S.C. §112, first paragraph.

Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. §112, first paragraph be reconsidered and withdrawn.

In the Office Action, Claims 1, 4, 7-11, 14, 18-20 and 27-33 are rejected under 35 U.S.C. §112, second paragraph as being indefinite. Specifically, the Patent Office alleges that the claims recite “an effective amount of menthol” and it is “unclear if ‘effective amount’ encompasses only the amount of ‘menthol’, or if it encompasses ‘menthol,’ a cooling agent and a heating agent combined.” See, Office Action, page 3, lines 13-18. The Patent Office also alleges that the term “cooling agents” has a conflicting definition with respect to the paragraph in

the specification that recites that a cooling agent may be selected from a markush group containing menthol. See, Office Action, page 3, line 19-page 4, line 3.

In response, Applicants have amended independent Claims 1, 11, 27 and 32-33 to recite, in part, consumable oral products, and the use thereof, comprising Erospicata oil, menthol, a cooling agent and a heating agent, wherein the menthol comprises at least 0.02% by weight of the total consumable oral product. The amendment is supported in the specification at, for example, Table 2. As such, Applicants respectfully submit that the rejections under 35 U.S.C. § 112, second paragraph, are now rendered moot. For at least the above-mentioned reasons, Applicants respectfully submit that Claims 1, 4, 7-11, 14, 18-20 and 27-33 fully comply with the requirements of 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. §112, second paragraph, be reconsidered and withdrawn.

In the Office Action, Claims 1, 4, 7-11, 14, 18-20 and 27-33 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2002/0119231 to Kumamoto et al. ("*Kumamoto*") in view of Plant Patent No. 8,645 to Sturtz ("*Sturtz*"). For at least the reasons set forth below, Applicants respectfully submit that the rejections be withdrawn.

Independent Claims 1 and 11 recite, in part, a product comprising Erospicata oil, an effective amount of menthol, a cooling agent and a heating agent, wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total product. Similarly, independent Claims 27 and 32 recite, in part, a method comprising the steps of adding to a product Erospicata oil, an effective amount of menthol, a heating agent and a cooling agent, wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total product. Independent Claim 33 recites, in part, a method of reducing the amount of peppermint flavor required to achieve an organoleptic effect in a product comprising the steps of manufacturing the product with Erospicata oil, an effective amount of menthol, a cooling agent and a heating agent, wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total product.

The present claims provide a product including Erospicata oil, a non-menthol cooling agent and an effective amount of menthol. See, specification, page 1, paragraph 4; paragraph 12, lines 1-4; page 2, paragraph 19. The unique combination of Erospicata oil and a non-menthol cooling agent provides a novel flavor which reduces the cost of peppermint-flavored products. See, specification, page 1, paragraph 4, lines 6-12; paragraph 5, lines 1-6. Menthol may also be

included in the product as an additional flavoring agent to kill germs. See, specification, page 6, paragraph 68, lines 1-2 and 6-12. Furthermore, by including the Erospicata oil in an amount between 0.01% and 5% by weight of the product, the product provides a unique flavoring benefit. See, specification, page 2, paragraph 22; page 5, paragraph 54, lines 1-3; Tables 1-2 and 6. In contrast, the cited references fail to disclose a product comprising Erospicata oil, an effective amount of menthol and a cooling agent, wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total product for at least the reasons set forth below.

Applicants respectfully submit that the cited references fail to disclose or suggest a product comprising Erospicata oil, an effective amount of menthol and a cooling agent as required, in part, by all of the independent Claims 1, 11, 27 and 32-33 and Claims 4, 7-10, 14, 18-20 and 28-31 that depend therefrom. The Patent Office asserts that *Sturtz* discloses an effective amount of menthol merely because the Erospicata oil contains 1% menthol. See, Final Office Action dated December 1, 2008, page 4, lines 19-21. However, contrary to the Patent Office's assertion, *Sturtz* does not disclose that its Erospicata oil contains 1% menthol but rather a maximum of 1% menthol. See, *Sturtz*, column 2, lines 14-15; column 3, lines 5-15; Table 6. Table 1 shows that the actual weight percent of menthol in the Erospicata oil is only 0.05%. See, *Sturtz*, Table 1. Furthermore, Applicants note that the weight percent of menthol is only 0.05% of the Erospicata oil. See, *Sturtz*, Table 1. Therefore, if the weight percent of menthol is 0.05% of the Erospicata oil, and the Erospicata oil comprises only 0.01% to 5% by weight of the total product, the amount of menthol in the total product as a result of the Erospicata oil is only between 0.000005% and 0.0025%. Applicants respectfully submit that one of ordinary skill in the art would understand that such an amount is not an effective amount within the meaning of the present claims.

Sturtz is entirely directed to a low-menthol Erospicata plant. See, *Sturtz*, Title; Abstract, lines 1-4; Column 1, lines 19-26. Although *Sturtz* discloses that its Erospicata oil may contain a small amount of menthol, nowhere does *Sturtz* disclose that its Erospicata oil contains an effective amount of menthol, nor does the Patent Office cite support for such claimed element. See, *Sturtz*, column 2, lines 9-15. In fact, *Sturtz* expressly states that "menthol is substantially absent from the oil." See, *Sturtz*, column 2, lines 29-32. Moreover, *Sturtz* teaches that "[t]he low menthol content of the essential oil is important because menthol is an alcohol that irritates nasal, oral and gastrointestinal epithelium." As such, Applicants respectfully submit that one of

ordinary skill in the art would understand that *Sturtz* is entirely directed to as low a menthol content as possible and would thus not include an effective amount of menthol. Therefore, *Sturtz* fails to disclose an effective amount of menthol.

Furthermore, *Kumamoto* fails to disclose an effective amount of menthol and a cooling agent within the meaning of the present claims. The Patent Office asserts that *Kumamoto* teaches using menthol but that other non-menthol cooling agents may be used. See, Non-Final Office Action dated February 5, 2008, page 4, lines 19-22; page 5, lines 1-3. However, Applicants respectfully submit that *Kumamoto* fails to disclose using menthol and a non-menthol cooling agent as required, in part, by the present claims. The present Specification expressly states that “[c]ooling agents, for the purpose of the present invention are defined as non-menthol cooling agents.” See, specification, page 1, paragraph 4, lines 10-12. Therefore, the effective amount of menthol in the present claims cannot be included in the non-menthol cooling agent.

Kumamoto is entirely directed to warming compositions including a cooling agent and a small amount of a compound represented by formula (I) and/or a warming agent. See, *Kumamoto*, page 1, paragraph 7, lines 1-9. The only disclosure of menthol in *Kumamoto* is the statement that “[s]pecific examples of the cooling agents which are preferably used in the invention include. . . menthol, isopulegol, . . . and spearmint oil.” See, *Kumamoto*, page 2, paragraph 26. Therefore, *Kumamoto* merely discloses using menthol as a cooling agent. However, nowhere does *Kumamoto* disclose using menthol and a non-menthol cooling agent. Instead, *Kumamoto* either discloses menthol or a non-menthol cooling agent, but not both. If the Patent Office relies on *Kumamoto* for the disclosure of a non-menthol cooling agent, *Kumamoto* thus fails to disclose an effective amount of menthol. Conversely, if the Patent Office relies on *Kumamoto* for the disclosure of menthol, *Kumamoto* fails to disclose a non-menthol cooling agent. Therefore, Applicants respectfully submit that *Kumamoto* fails to disclose an effective amount of menthol and a cooling agent as required, in part, by the present claims.

Further, Applicants respectfully submit that the cited references also fail to disclose or suggest a product comprising Erospicata oil, wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total product as required, in part, by all of the independent Claims 1, 11, 27 and 32-33 and Claims 4, 7-10, 14, 18-20 and 28-31 that depend therefrom. In response to Applicants’ argument that the cited references fail to disclose the claimed range of Erospicata oil in the product, the Patent Office, citing the MPEP, merely asserts that changes in result

effective variables are generally not patentable because experimentation to find an optimum range involves no more than routine skill in the art. See, Final Office Action dated December 1, 2008, page 4, lines 21-22; page 5, lines 1-3. However, the portion of the MPEP relied upon by the Patent Office expressly states that “[a] particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.” See, MPEP Section 2144.05.II (2009). Nowhere does either *Sturtz* or *Kumamoto* disclose that Erospicata oil is incorporated into an oral product to achieve a novel flavor. Instead, *Sturtz* merely discloses that Erospicata oil has a characteristic peppermint taste and smell, rather than a novel flavor when combined with a cooling agent. See, *Sturtz*, column 2, lines 5-7. Moreover, *Kumamoto* fails to disclose Erospicata oil at all. As such, the cited references fail to recognize that the amount of Erospicata oil in an oral product affects the novel flavor achieved. Therefore, Applicants respectfully submit that the claimed range of Erospicata oil is not a matter of routine experimentation and, thus, is patentable over the cited references.

Moreover, Applicants submit that one of ordinary skill in the art would have no reason to combine the cited references because *Sturtz* teaches away from both *Kumamoto* and the present claims. *Kumamoto* is entirely directed to an oral composition including a combination of a cooling agent with a warming agent or a compound of formula (I). See, *Kumamoto*, page 1, paragraph 7, lines 1-9; ; paragraphs 8-10; paragraph 14, lines 1-5. *Kumamoto* specifically teaches that its cooling agent may include menthol. See, *Kumamoto*, page 2, paragraph 26, lines 1-3. Similarly, the present claims require an effective amount of menthol in an oral consumable product.

In contrast, *Sturtz* is entirely directed to providing as low a menthol content as possible while also providing peppermint-like organoleptic properties. See, *Sturtz*, column 2, lines 28-31. *Sturtz* specifically teaches that menthol is undesirable in ingestible products “because menthol is an alcohol that irritates nasal, oral and gastrointestinal epithelium.” See, *Sturtz*, column 2, lines 24-28. In fact, *Sturtz* states that menthol is “substantially absent from the oil” and that “[t]he low menthol content of the essential oil is important” to avoid nasal and gastrointestinal problems. See, *Sturtz*, column 2, lines 24-26 and 28-31. Thus, *Sturtz* teaches away from using any menthol in ingestible products as disclosed by *Kumamoto* and the present claims.

The Patent Office asserts that one of ordinary skill in the art would combine *Sturtz* and *Kumamoto* “to be able to use menthol as a cooling agent while still having a strong peppermint flavor without using a lot of peppermint oil, which adds additional menthol.” See, Final Office Action, page 3, lines 14-16. However, as discussed previously, *Sturtz* teaches away from the use of any menthol in ingestible products, regardless of whether the menthol is used as a cooling agent. *Sturtz* expressly states that menthol, without any limitation as to what the menthol is used for, “irritates nasal, oral and gastrointestinal epithelium.” See, *Sturtz*, column 2, lines 24-28. Nowhere does *Sturtz* disclose or suggest that menthol is desirable if it is used as a cooling agent. As such, *Sturtz* teaches away from the use of any menthol in oral consumable products.

In response to Applicants’ argument, the Patent Office asserts that “*Sturtz* does not teach not using menthol at all [but rather] an alternative to avoid too much menthol being used.” See, Final Office Action, page 3, lines 18-19. As support for its assertion, the Patent Office notes that although menthol is not abundant in the Erospicata oil of *Sturtz*, it is present. See, Final Office Action, page 3, lines 20-22. However, the Patent Office ignores the express teaching in *Sturtz* that “the absence of [menthol] helps avoid nasal and gastrointestinal irritation.” See, *Sturtz*, column 2, lines 31-33. Although the Erospicata oil of *Sturtz* may contain a very small amount of menthol (only 0.05%, which *Sturtz* describes as being “substantially absent” from the oil), *Sturtz* expressly teaches away from using any additional menthol apart from that present in the Erospicata oil. See, *Sturtz*, column 2, lines 24-34; Table 1. Furthermore, for reasons discussed previously, the amount of menthol present in the Erospicata oil does not constitute an effective amount of menthol in accordance with the present claims. As such, additional menthol must be used along with the Erospicata oil to achieve an effective amount of menthol. However, by expressly disparaging the use of menthol in ingestible products, *Sturtz* teaches away from using menthol as a cooling agent in addition to its Erospicata oil or using an effective amount of menthol.

The Patent Office further asserts that one of skill in the art would be motivated to use the Erospicata oil of *Sturtz* instead of peppermint oil “to obtain the peppermint taste while avoiding a bitter taste and being able to add menthol in the desired amount to achieve its benefit without adding too much menthol.” See, Final Office Action, page 4, lines 7-10. However, nowhere does *Sturtz* disclose how much menthol would be “too much” to use in an ingestible product, nor does the Patent Office cite support for such assertion. Instead, contrary to the Patent Office’s

assertion, *Sturtz* discloses that adding menthol generally to an oral product causes nasal and gastrointestinal irritation. See, *Sturtz*, column 2, lines 24-26. As such, *Sturtz* teaches away from adding any menthol, beyond what is present in its Erospicata oil, to an oral product.

The Patent Office also asserts that one of ordinary skill in the art would simply recognize when menthol is suitable and unsuitable for use and would reasonably choose one of the non-menthol cooling agents of *Kumamoto* when menthol is not suitable. See, Final Office Action dated December 1, 2008, page 4, lines 14-19. However, even if such assertion is true, Applicants respectfully submit that *Sturtz* still teaches away from using menthol as disclosed by *Kumamoto* and the present claims. The Patent Office cannot pick and choose specific teachings of the references to meet the claimed limitations but rather must consider the teachings of each reference as a whole. See, MPEP Section 2142 (2009). Regardless of which cooling agent one of ordinary skill in the art may choose, the fact remains that *Sturtz* as a whole expressly teaches away from using any menthol in addition to that contained in its Erospicata oil. See, *Sturtz*, column 2, lines 24-28. Because *Kumamoto* discloses that menthol may be used as a cooling agent, Applicants respectfully submit that *Sturtz* teaches away from *Kumamoto*. Furthermore, as discussed previously, *Sturtz* teaches away from an effective amount of menthol as required by the present claims. Because *Sturtz* is entirely directed to an oil with as low a menthol content as possible to avoid gastrointestinal and nasal irritation, *Sturtz* teaches away from adding menthol to an oral product as taught by *Kumamoto* and the present claims.

In sum, the Patent Office has failed to consider the cited references as a whole including those portions teaching against or away from each other and/or the claimed invention. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443, 448-49 (Fed. Cir. 1986). “A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by [Applicants].” *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998). Specifically, the Patent Office has continued to ignore the express teaching in *Sturtz* that menthol is undesirable in oral products “because menthol is an alcohol that irritates nasal, oral and gastrointestinal epithelium.” See, *Sturtz*, column 2, lines 24-28. Because *Sturtz* teaches away from *Kumamoto* and the present claims, one of ordinary skill in the art would have no reason to combine the cited references to arrive at the present claims.

For at least the reasons discussed above, the combination of *Kumamoto* in view of *Sturtz* is improper because the skilled artisan would have not reason to combine the cited references. Moreover, the cited references fail to disclose or suggest every element of the present claims and thus fails to render the claimed subject matter obvious.

Accordingly, Applicants respectfully request that the obviousness rejections with respect to Claims 1, 4, 7-11, 14, 18-20 and 27-33 be reconsidered and the rejections be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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